result in expulsion of the implant". To mitigate these problems, embodiments of the invention are configured to promote soft tissue ingrowth in order to create an infection resistant barrier around the percutaneous penetration site. (See specification page 5, lines 3 through 19.) More particularly, embodiments of the invention employ perpendicular longitudinal and lateral porous layers on the implanted device, at the percutaneous penetration site, having a pore size and porosity selected to promote soft tissue ingrowth.

Independent claim 1 recites the significant characteristics of the invention, i.e., *"A medical device comprising: a stud configured to project percutaneously outward through a patient's skin layers;..."* the stud outer end *"...having a longitudinal peripheral surface...having a longitudinal porous layer thereon for promoting soft tissue ingrowth; a surface oriented substantially perpendicular to said...peripheral surface...[that] has a lateral porous layer thereon oriented substantially perpendicular to said longitudinal porous layer for promoting soft tissue ingrowth; and wherein at least one of said porous layers is characterized by a pore size within the range of 50 to 200 microns with a porosity of between 60 to 95%."*

The Office Action rejects dependent claim 2 (whose limitations have now been incorporated into independent claim 1) under 35 U.S.C. 103(a) as unpatentable over Vito or Dahners in view of de Groot. Favorable reconsideration is requested because these references, taken alone or in combination, (1) fail to address the critical problem of mitigating infection around the percutaneous penetration site of an implanted device, and (2) lack any suggestion of providing the structural solution described and claimed herein. Moreover, as will be discussed further herein, the cited references lack any motivation for the combination proposed by the Office Action. That is, as set forth in MPEP Section 2143.01, Subsection I, "Obviousness can only be established by combining or modifying the teachings of the prior

art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so". "The teaching, suggestion, or motivation must be found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." It is urged that no such teaching, suggestion, or motivation can be found in the cited references. Rather, it is submitted that the references more likely teach away from the proposed combination because a modification of Vito or Dahners in view of de Groot would appear to reduce the effectiveness of the Vito and Dahners devices for their intended purpose.

Vito is directed to an orthopedic device intended to prevent screws from loosening and migrating out of a patient's bone. More particularly, Vito teaches a fixation assembly for orthopedic applications comprised of a screw 10 having a shank portion 40, a recessed middle section 35, and a lower threaded section 45. A locking ring 30 surrounds the recessed middle section. The screw and locking ring combination is used to attach an orthopedic plate 20 to a bone 50. Vito comments that "The screw 10 is preferably made of titanium or stainless steel with a porous coating to promote bone growth".

It is apparent from reading Vito that his fixation assembly is intended for subcutaneous implantation to hold plate 20 against bone 50 so that "...the screw cannot loosen or migrate out of the bone...". Nothing in Vito suggests that any part of his fixation assembly is configured to project percutaneously through a patient's skin layers. If there is no percutaneous projection, then the Vito device would not encounter the problems of soft tissue downgrowth, sinus tract formation, and marsupialization addressed by Applicants. Without these problems, why would Vito be motivated to modify his device in view of de Groot?

De Groot describes a percutaneous implant comprising a subcutaneous part 1 and a

percutaneous part 10. The subcutaneous part 1 comprises a mesh sheet 2 intended to be placed in soft tissue for promoting tissue ingrowth for anchoring a holding member 3. De Groot's mesh sheet 2 is similar in pore size and porosity to the porous layer recited in Applicants' claim 1. But would it be obvious to substitute de Groot's mesh for Vito's porous layer? Unquestionably not. What could be the reason? Where is the motivation? In fact, if the relatively loose mesh of de Groot were used in place of the Vito porous layer, it would compromise the fixation function of the Vito device. As noted in MPEP Section 2143.01, Subsection V, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.

Accordingly, it is respectfully urged that Applicants' invention as now recited in claim 1 is not made obvious by the Vito and de Groot teachings.

The Dahners reference is similar to Vito in that it too is directed to an orthopedic device for fixing a surgical plate to a bone with a screw. More particularly, Dahners describes particularly configured fasteners, or screws, and plate apertures which allow for multi-angular insertion of the screws to better fixate the plate to the bone. As with Vito, nothing in Dahners suggests that any part of his fastening apparatus is configured to project percutaneously through a patient's skin layers. Nor is Dahners concerned with anchoring or preventing infections in soft tissue. Accordingly, the Dahners device would not encounter the problems of soft tissue downgrowth, sinus tract formation, and marsupialization. Consequently, Applicants are unable to find any teaching, suggestion, or motivation in Dahners, or the aforedescribed de Groot reference, for modifying the Dahners device to use the de Groot mesh. As observed in MPEP Section 3143.01, Subsection III, "The mere fact that references

can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination". To the extent that Dahners refers to a porous matrix, it functions only in the tappable contact region for allowing multi-angular orientation of the fastener 10 and not for promoting soft tissue ingrowth.

Accordingly, it is respectfully urged that the invention as now recited in claim 1 is not made obvious by the Dehners and de Groot teachings.

Independent method claim 16 now includes the limitations of cancelled dependent claim 17 with regard to the pore size and porosity characteristics of the perpendicular porous layers. As with claim 2, claim 17 was rejected under 35 U.S.C. 103(a) as unpatentable over Vito or Dahners in view of de Groot. Favorable reconsideration and allowance of claim 16 is now courteously requested for the same reasons as were urged with respect to claim 1.

The Examiner's comments in the Office Action regarding each of the Vito, Dahners, and de Groot references have been carefully considered. With regard to Vito, the Examiner states that "Vito discloses a medical device and method comprising ...a stud (10) configured to project percutaneously outward through a patient's skin layers..." Reconsideration is courteously requested because, in fact, element 10 in Vito comprises a screw which is intended to secure a plate (20) to bone (See column 1, lines 41 through 57.) Vito does not contemplate any percutaneous application. Rather, it appears clear that Vito's assembly is intended to be located entirely subcutaneously.

As with Vito, the teachings of Dahners relate to the use of bone screw/plate systems for orthopaedic surgical procedures in which the entire assembly is located subcutaneously. Although the Office Action asserts that Dahners discloses a medical device comprising a stud "...configured to project percutaneously outward through a patient's skin layers," Applicants

are unable to find such a disclosure in Dahners. The Office Action further suggests that Dahners discloses a "...peripheral surface having a longitudinal porous layer thereon for promoting soft tissue in-growth..." Respectfully, Dahners' porous layer comprises a fiber metal matrix only used in a "...tappable contact region..." (Column 2 lines 60-64) for permitting the screw to be tapped into the bone at an angle different than into the plate. (Column 3 lines 40-52). The Dahners' porous fiber metal matrix is used only for ease of tapping screw threads, unrelated to any issue of promoting soft tissue ingrowth (Column 2 lines 39-58). Also, Dahners' "means for promoting healing" mentioned by the Examiner is attributable only to the increased stability of Dahners' apparatus, not to any soft tissue ingrowth.

For the foregoing reasons, favorable reconsideration of claims 1, 3-9, 13-16, and 18-21 is courteously requested.

Respectfully submitted,

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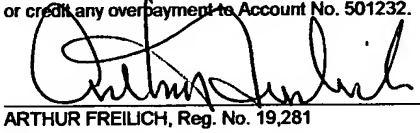

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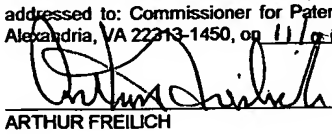

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